Presentation to the
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More Generic Pharmaceutical Utilization, Not Unregulated Drug Importation, Answers America's Drug Cost Crisis

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GPhA Testimony: HHS Task Force on Drug Importation

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Testimony of Kathleen Jaeger
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My name is Kathleen Jaeger, and I am President and CEO of the Generic Pharmaceutical Association. On behalf of GPHA and its more than 140 members, I thank you for the opportunity to provide comments on the issue of drug importation.

GPHA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our products are used to fill more than one billion prescriptions every year. No other industry has made, nor continues to make, a greater contribution to affordable health care in this country than the generic pharmaceutical industry.

INTRODUCTION:

GPhA and its members recognize the significant burden that pharmaceutical and healthcare costs impose on American consumers, healthcare providers and public policy makers at the federal, state and local level.

For more than two decades, FDA-approved generic pharmaceuticals have played a critical role in the effort to contain rising prescription drug costs. In 1984, when the Hatch-Waxman Amendments became law, America faced a health care cost crisis similar to the one it faces today. Since that time, the generic pharmaceutical industry has matured and has provided billions of dollars in savings each year, while improving the health of millions of Americans.

We are testifying before this Task Force because we share the public's concerns about access to affordable medicine, but we also know that any long-term solution

to high costs must not sacrifice safety or quality of our medicines. These are assurances that can only be offered through the strict approval process and regulation of the U.S. Food and Drug Administration (FDA).

Accordingly, GPhA opposes the importation of pharmaceuticals that have not been under the continuous regulatory oversight of FDA. We strongly believe that because of their uncertain safety and efficacy, unregulated foreign imports are not a viable solution to high prescription drug costs. Rather, GPhA believes that the solution to this important issue starts with regulated, FDA-approved generic pharmaceuticals. We believe federal and state governments could immediately and substantially lower prescription drug costs for all Americans by taking steps to increase the timely introduction and utilization of FDA-approved generic medicines.

Today, FDA-approved generics account for more than 51% of all prescriptions filled in the United States. Yet, generics represent less than eight cents of every dollar consumers spend on prescription drugs. These savings are in no small part the result of our Nation's commitment to free market principles. Indeed, our free market principles have been the major force in creating today's robust and competitive U.S. generic pharmaceutical industry.

Our industry's success, and the resulting consumer savings, stand in stark contrast to the economic experiences of other countries, such as Germany, France and Italy, which undermine pharmaceutical competition by government regulation and, hence, competitive pricing. If we permit the unregulated importation of prescription drugs, we will in effect, abandon the free market principles that have been so instrumental in allowing the generic industry to provide cost-effective prescription drugs. In turn, this could disrupt this Nation's balance between innovation and access in the prescription drug arena. In addition, unregulated importation could undermine the 180-day generic drug exclusivity period that provides the critical incentive for generic companies to challenge invalid patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent.

Finally, importation without adequate safeguards could shred the fabric of FDA's safety net that has protected consumers from the importation of unregulated drugs of questionable safety, potency and quality for more than 70 years. Opening our Nation's borders, without a comprehensive system of FDA oversight and enforcement likely will allow counterfeit, adulterated, misbranded and unapproved

drugs into this Nation's secure drug supply and ultimately into consumer medicine cabinets.

CONSUMER SAFETY MUST BE PARAMOUNT:

U.S. product approval and manufacturing standards have evolved over the past 65 years in an effort to protect the health and welfare of Americans. Today, the quality of America's prescription medicines is by far the highest in the world. Importation of unregulated drug products could significantly undermine this quality standard that we have worked so hard to achieve. For instance, the Canadian regulatory system exempts from its health and safety standards, drugs manufactured for "export only." As a result, there can be no assurance of the actual origin of the drugs that are imported from Canada unless there is FDA supervision.

Also, there is no current system to determine whether unregulated imported drugs meet basic quality standards, or whether they have long since passed their expiration date, or are sub-potent, improperly labeled, contaminated or counterfeit. Nor are there adequate enforcement tools to stop importers of identified adulterated, misbranded or counterfeit products from re-attempting entry into the United States. Simply put, unless and until FDA has sufficient oversight over all drug importations, this Nation's drug supply chain is vulnerable to an influx of inferior and/or potentially dangerous medicines. Adequate patient safeguards therefore must first be in place to assure that unregulated imported products meet all applicable U.S. standards as a prerequisite of importation. *Otherwise, inferior and potentially lethal products may be sold unknowingly to American consumers at local pharmacies, and manufacturers of FDA-regulated imported products may be discriminated against in the U.S. marketplace.*

Another critical issue for consideration is whether FDA will have the requisite resources to oversee a comprehensive import program. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this Nation's drug supply system remains secure. Given the necessity of developing a costly regulatory program to govern importation to ensure consumer safety, the purported cost savings of importation may never be realized.

COST SAVINGS QUESTIONABLE:

The cost savings that proponents suggest will result from unregulated importation are questionable at best.

With importation, consumers unknowingly may end up paying more than they would if they bought an equivalent FDA-approved generic pharmaceutical here in the United States. In fact, several reports suggest that, on average, U.S. generic drugs are more affordable than Canadian generics.[1] Given the additional costs of unregulated importation, an assessment of the scope of potential products for importation seems prudent. Such an assessment would provide a means of ensuring consumer cost savings. Indeed, it seems counterintuitive to permit importation of unregulated imports if there is a less expensive generic already available to consumers here at home. At a minimum, unregulated prescription drug importers should be required to establish that the proposed imported product has no lower cost generic equivalent approved in the United States. Moreover, cost savings from importation should be required to be passed along to the consumer. Without this additional requirement, commercial entities could take much of the difference in prices for themselves, leaving little or no cost savings for the U.S. consumer, all the while increasing risk, adding additional costs to the government, and potentially enhancing manufacturer liability.

More importantly, unregulated importation will destroy the 180-day generic exclusivity incentive, causing our healthcare system to forfeit substantial future cost savings. This critical healthcare provision plays a significant cost containment role because it provides generic manufacturers with an incentive to challenge questionable and invalid patents. The 180-day provision has been instrumental in bringing consumers affordable medicines in an accelerated fashion, while saving billions of dollars in pharmaceutical costs. For example, 11 successful generic challenges provided over $27 billion in savings.

In addition, with no mechanism in place to ensure consumer safety, the potential cost savings, if any, would be seriously diminished by distribution and liability costs. Importation ignores the potential costs associated with medical treatment for consumers who have obtained poor quality drugs that don't work. It ignores the costs associated with treating consumers of unregulated drugs that are contaminated or contain harmful ingredients. It ignores the cost of treating

[1] Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002 John R. Graham and Beverly A. Robson, The Fraser Insitute, "Prescription Drug Prices in Canada and the United States – Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5

consumers taking unregulated imported drugs that are improperly labeled. The costs of restoring America's healthcare system after importation opens the floodgate to questionable medicines must be calculated and seriously considered before any action is taken.

The current push towards importation also ignores potential liability issues and the complexity of these issues. Policymakers must explore the question of who should assume the risk in a system without the same assurances (i.e., should liability be placed on the importer or end-user rather than the original manufacturer or the manufacturer believed to have produced the drug). Lastly, we have yet to determine the costs to regulated imported drugs as a result of implementing an import program for unregulated drugs. Whether an importation system would impose additional needless requirements on, or result in a negative impact to, the availability of regulated imported drug products or their continued manufacture in the United States also is a question that must be addressed. For example, our industry imports many of our products and raw materials. These are safe, regulated medicines available at a lower cost. Timely access to these products should not be inadvertently hindered by additional requirements intended to address previously unregulated products. Additional questions must be asked, and resolved, before importation is permitted. What would be the additional costs to consumers … to our healthcare system? Would these costs outweigh the potential savings derived from importation? All of these issues should be factored into any savings projections on this issue.

IMMEDIATE AND AVAILABLE SOLUTIONS FOR LOWERING PRESCRIPTION DRUG COSTS:

GPhA recognizes that many policymakers are searching for proposals to make prescription drugs more affordable. GPhA believes that the solution to high prescription drug costs will not be found in unregulated foreign imports. Rather, Americans can have safe and affordable prescription drugs through greater utilization of FDA-approved generic prescriptions.

Generic pharmaceuticals are a safe, reliable solution to the problem of increased costs of prescription drugs. While a limited program of importing drugs from selected countries would potentially lower some drug costs for those without prescription drug coverage, increasing access to generic drugs would benefit all consumers, businesses, and government purchasers, through lower out-of-pocket and insurance costs.

The tools to immediately increase generic drug utilization and the savings it provides include: (1) educating consumers, physicians and states about the availability of affordable generic alternatives; (2) encouraging substitution of less expensive and equivalent generics; (3) employing benefit designs that incentivize the use of generics; and (4) ensuring the timely entry of generics into the marketplace.

Every 1% increase in generic utilization will result in nearly a 1% increase in savings for prescription drug payers. GPhA believes one answer to lowering prescription drug costs will be found in removing obstacles to improve access to generic medicines that already have FDA scrutiny, and already save consumers more than $10 billion each year.

FDA plays an important role in ensuring that American consumers have access to generics through its generic drug review and approval process. Yet, the Office of Generic Drugs, which is responsible for the approval of generic medicines, is receiving no additional funding this year. This is significant given that the number of generic drug applications continues to rise significantly, while the number of new drug applications is declining. Equally important is the fact that the review and approval of generic applications currently takes longer, on average, than the approval of new drugs, potentially delaying consumer access and savings. Congress and the Administration need to address the issues of increasing the resources necessary to approve generic drugs more efficiently, and of making generic approvals a priority, rather than creating an expensive new regulatory mechanism to monitor the importation of unregulated drugs.

Congress and the Administration also must focus attention on establishing a definitive process pursuant to which generic versions of expensive bio-pharmaceuticals can receive approval. Last year, bio-pharmaceuticals cost payers more than $21 billion. Generic versions of these important, but expensive drugs would contribute additional billions of dollars a year in prescription drug savings.

The Administration and states also could work together to ensure that aggressive generic substitution tools are employed in state Medicaid programs. States could garner additional savings by implementing aggressive generic substitution tools to other state senior supplemental programs and employee health programs.

SUMMARY:

At a time when federal, state and local governments are working vigorously to bolster homeland security, it is the position of the GPhA that it is unwise to adopt any proposal that would strip FDA of its ability to assure the safety and efficacy of prescription drugs. Without FDA oversight of unregulated drug importation, which at best will be expensive to implement and difficult to ensure, the U.S. drug supply chain would be particularly vulnerable to abuse. The result of importation could be an influx of adulterated, misbranded, unapproved or counterfeit medicines into this Nation's drug supply chain. While it is understandable that consumers facing high costs for prescription drugs are seeking relief, sacrificing safety for affordability is shortsighted, dangerous and unnecessary.

As Congress and the Administration consider importation of unregulated drugs, GPhA strongly encourages these parties to look for immediate solutions in increased usage of generic medicines. We also encourage individuals to be smart consumers, and take advantage of the immediate cost savings on safe and effective, FDA-approved generic medicines. To this end, GPhA is committed to developing a Web site to alert consumers on affordable, FDA-approved generic alternatives are available in the United States.